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(19)

(54) EDIBLE OILS HAVING HYPOCHOLESTEROLEMIC PROPERTIES

(71) We, THE PROCTER & GAMBLE COMPANY, a Corporation organised and existing under the laws of the State of Ohio, United States of America, of 301 East Sixth Street, Cincinnati, Ohio 45202, United States of America, do hereby declare this invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to edible oil compositions and foodstuffs comprising such oils.

The oil has dissolved therein a plant sterol to give the oil hypocholesterolemic activity. As used herein, the term "hypocholesterolemic" means reducing the cholesterol level in the blood of warm-blooded animals or inhibiting or reducing the build up of cholesterol in the blood. The term "plant sterol" includes all non-animal sterols, that is, not only phytosterols (plant sterols characteristic of higher plants) but also mycosterols (plant sterols from lower plants). For a more complete description of plant sterols, see Deuel, Jr. Harry J., *The Lipids, Volume 1,* Interscience Publishers (New York—1951) at pages 321 and 348. These compositions may generally remain clear at normal home refrigerator temperatures. The added plant sterols show resistance to precipitation from the oil in the presence of water, for example, when a vinegar and oil emulsion is prepared. Thus, the plant sterols can be added to the oils in effective amounts without affecting the appearance of the oils.

The addition of hydrocholesterolemic additives, including plant sterols and plant sterol esters, to oil is old. [See U.S. Patents 3,085,939 and 3,203,862; Canadian Patent 567,202; and Peterson, et al., *50 Journal of Nutrition* 191—201 (1953)]. Belgium patent 753,648 relates to clear cooking and salad oils having hypocholesterolemic properties. The Belgium patent teaches the enhanced solubility of plant sterol esters over the free sterol in edible oils. The above-mentioned U.S. Patent 3,085,939 relates to a pharmaceutical composition comprising a water-oil emulsion which contains plant sterols and certain emulsifing agents among which the free fatty acids.

A serious problem has arisen because plant sterols characteristically have very limited solubility in any solvent system, and even less in edible oils. But in order for edible oils to exhibit hypocholesterolemic properties to a useful extent, it is necessary that the hypocholesterolemic agent (in this case the plant sterols) be present in true solution in the edible oil base in an amount of from 2.0 to 6.0% by weight. It is also desired that oils containing plant sterols should remain clear at normal home refrigerated temperatures, and that the added sterol should not precipitate from the oil at reduced temperatures. Also, it is desired that the added sterol should resist precipitation from the oil on the addition of water.

This invention makes it possible to provide edible oil compositions, such as salad and cooking oils, and foodstuffs comprising them, which satisfy some or all of the above desiderata.

According to the invention a food composition comprises an edible oil in admixture with (a) from 2.0 to 6.0% by weight of composition of a plant sterol; (b) from 0.5 to 15.0% by weight of composition of a solubilizing agent which is a saturated or unsaturated fatty acid having from 6 to 18 carbon atoms, a monoester of such a fatty acid with a polyhydric alcohol, or an alkanol having from 6 to 18 carbon atoms.

The oil may be a mixture of edible oils, the plant sterol may be a mixture of plant sterols. The solubilizing agent may be a mixture of the defined solubilizing agents.

It is accepted that an elevated cholesterol concentration in the circulating body plasmas indicates a set of metabolic abnormalities which frequently manifest an atheroselerotic condition. It is also accepted that exogenous

cholesterol introduced from the gut to the circulating plasmas advances, possibly causes, athersoclerotic disease. Consequently, various means to prevent the absorption of cholesterol from the gut have been proposed. Conspicuously successful among these means is the utilization of plant sterols in dietary compositions. However, there is no unanimous agreement as to how plant sterols act in reducing the absorption of cholesterol from the gut. This lack of unanimity probably indicates that plant sterols function by more than one mechanism in the overall suppression of cholesterol absorption.

The present invention makes available a group of food compositions which increase the field of use of plant sterols in the suppression of cholesterol absorption. These oil-based food compositions comprise an inherently non-absorbable plant sterol, and a solubilizing agent for such sterol.

The mechanism which is central to this invention may be appreciated from the following comments: It is known that oil is essential for the absorption of cholesterol. Further, it is known that cholesterol is transported from an oil-solubilized form in the intestine to the mucosal cells for absorption into the lymph. The steps leading to ultimate absorption may generally be stated as follows: A cholesterol bearing oil phase is progressively dispersed as minute oil droplets in the predominately aqueous food mixture during passage from the stomach to the small intestine. Thereafter, emulsifying agent such as bile acids, fatty acids, and mono-glycerides thereof progressively attack the discrete oil droplets to form colloidal micelles which are presented to the mucosal cells for absoprtion of their lipid components. Fats and oils, however, are preferentially taken from the discrete oil droplets by the emulsifying agents. The results is that the steroid components of the oil droplets undergo a relative enhancement in concentration as micelle formation proceeds. Since steroids are so difficulty soluble, a condition of saturation is soon reached whereupon crystallization of the steroids commences. It has been established that crystalized steroids cannot again be effectively solubilized for absorption. Consequently, the crystalized steroids are excreted.

Inherently non-absorbable steroids such as certain plant sterols and their carboxylic acid esters effectively promote the crystallization of cholesterol from the oil droplets by competing with cholesterol for occupancy in the oil droplet. The overall result is that a state of saturation with respect to cholesterol is reached thereby initiating its crystallization.

A problem which has beset the art is that the inherently non-absorbable steriods are, as is cholesterol, exceedingly difficult to solubilize in dietary compositions such as salad and cooking oils. Consequently, the art has not been able to fully exploit the above mechanism in suppression the absorption of cholesterol. The present invention solves this problem by incorporating into dietary compositions certain steroid solubilizing agents such that greater concentrations of inherently non-absorbable steriods may be incorporated into such dietary compositions.

The principal dietary compositions encompassed by this invention are cooking and salad oils. The invention also contemplates oil foods including such oils, for example oleaginous gel foodstuffs such as peanut butter, mayonnaise, ice cream, and margarine spreads.

Suitable solubilizing agents for the plant steroids may be selected from nontoxic compounds such as alcohols, free fatty acids, and simple esters of such fatty acids such as monoglycerides.

The components of the edible compositions of this invention, namely the oil base, the plant sterol, and the solubilizing agent, are described in greater detail below. Also described are recommended procedures for combining the above mentioned components to yield the food compositions of this invention. And lastly there is presented a series of examples featuring the hypocholesterolemic edible oils of this invention.

The edible oil base may be any of a wide variety of clear, liquid glyceride oils. Pure triglycerides liquid at normal home refrigerator temperatures, such as triolein, are suitable. Also included among suitable oils are the so-called natural salad oils, for example olive oil, sunflower seed oil, safflower oil and sesame seed oil. Other naturally occurring liquid glyceride oils such as cottonseed oil and corn oil are also useful; these oils are generally given a preliminary "winterization", dewaxing, or similar treatment to remove the higher melting stearines before being used as an oil base. Certain other oils such as soyabean oil can be partially hydrogenated before use to improve their resistance to oxidative deterioration during prolonged storage periods; the higher melting solids formed during the hydrogenation treatment are preferably removed by winterization.

Suitable clear liquid glyceride base oils can also be obtained by directed, low temperature interesterification or rearrangement of animal or vegetable fatty materials, followed by removal of the higher melting solids formed during the reaction. For an example of this procedure, see U.S. Patent 2,442,532. Another group of suitable oils includes those in which one or more short-chain fatty acids, such as acetic acid and propanioc acid, partly replace the long chain fatty acids present in natural triglyceride oils.

Other useful clear liquid glyceride oils can be derived from animal, vegetable and marine sources, including mixture of various of such oils. Particularly preferred oils for use in this invention are triolein, cottonseed oil, soyabean oil, and mixtures thereof.

Examples of the plant sterols for use in this invention include α-sitosterol, β-sitosterol, stigmasterol, ergosterol and compesterol. Typically the solubility of the above-mentioned plant sterols in the above-mentioned glyceride base oils is in the range from 0.5 to 1.5% by weight. These concentration levels are too low to provide a noticeable hypocholesterolemic effect. However, by means of the solubilizing agent used in the present invention, the concentration plant sterol can be raised, so that it is possible to use the concentrations required by the present invention, that is 2.0 to 6.0% by weight of the plant sterol in the base oil.

The sterol solubilizing agents used in this invention are the fatty acids, alkanols, and esterified fatty acids (such as monoglycerides) defined above.

The suitable fatty acids are those having from 6 to 18 carbon atoms. For a more complete description of these fatty acids, see Markley, Klare S., *Fatty Acids, Part I*, Interscience Publishers, Inc. (New York, 1960). Saturated fatty acids containing more than 18 carbon atoms have a tendency to crystallize from an oil solution and hence are not suitable for use in the present invention. Examples of suitable fatty acids are oleic, stearic, palmitic, and lauric.

Examples of suitable fatty acid esters are sorbityl derivatives and glycerides, such as monoolein, monolaurin, monostearin, and monopalmitin.

Table I illustrates the enhanced solubility of certain plant sterols in liquid glyceride base oils occasioned by the presence of certain sterol solubilizing agents used in this invention.

TABLE I

Plant Sterol	Oil Base	Solubilizing Agent (% by weight)		Steroid Solubility (% by weight at 25°C)
β-Sitosterol	Triolein	Oleic Acid	5.0	3.5
β-Sitosterol	Triolein	Oleic Acid	10.0	3.8
β-Sitosterol	Triolein	Hexanoic Acid	5.0	4.0
β-Sitosterol	Soyabean Oil	Hexanoic Acid	10.0	5.0
Stigmasterol	Soyabean Oil	Lauric Acid	5.0	3.5

The composition of the invention can be prepared in any convenient way.

One way which has been found to give superior results involves the use of an intermediate solvent in which the plant sterol has a solubility greater than in the edible oil. Examples of such solvents are hexane, diethyl ether, and ethanol. The sterol is dissolved in the intermediate solvent and the resulting solution is mixed with the edible oil to which has been added the sterol solubilizing agent. Thereafter, the intermediate solvent may be removed by evaporation.

The concentration of the sterol is from 2.0 to 6.0% by weight, and the corresponding concentration of the steroid solubilizing agent is from 0.5 to 15.0% by weight of the food composition.

The edible oil compositions herein described may reduce the level of cholesterol in the blood that is directly of dietary origin by up to 65% compared with the case when no hypocholesterolemic additives are utilized.

The hypocholesterolemic edible oil compositions can be utilized as such for purposes of cooking and in salad dressings, or can be incorporated with other food ingredients to yield food products as diverse as mayonnaise and bread, and when they are utilized as an ingredient in other foods, their hypocholesterolemic activity may be retained.

The following Example illustrates the food compositions of this invention.

EXAMPLE

Two clear cooking and salad oil compositions are prepared by dissolving a free plant sterol in a liquid triglyceride edible oil. Table II shows the identity of the triglyceride, the concentration and identity of the plant sterol, and the identity and concentration of the sterol solubilizing agent. Both the compositions remain clear at normal home refrigerator temperatures (about 40°F). They also exhibit enhanced hypocholesterolemic properties.

TABLE II

Triglyceride	Plant Sterol (2.5% by weight)	Sterol Solubilizing Agent (5.0% by weight)
Soyabean Oil	β-Sitosterol	Oleic Acid
Corn Oil	β-Sitosterol	Lauric Acid

Results which are substantially equivalent to those obtained in Example I are obtained when the β-sitosterol is replaced by an equivalent of α-sitosterol, stigmasterol, ergosterol and campesterol, respectively.

Substantially equivalent results are also obtained when the sterol solubilizing agent is palmitic acid, stearic acid, monoolein, hexanol, monolaurin, monostearin and monopalmitin, respectively.

WHAT WE CLAIM IS:

1. A food composition comprising at least one edible oil in admixture with (a) from 2.0 to 6.0% by weight of composition of a plant sterol; (b) from 0.5 to 15.0% by weight of composition of a solubilizing agent which is a saturated or unsaturated fatty acid having from 6 to 18 carbon atoms, a monoester of such a fatty acid with a polyhydric alcohol, or an alkanol having from 6 to 18 carbon atoms.

2. The product of claim 1 wherein the food composition is a clear cooking and salad oil composition.

3. The cooking and salad oil composition of claim 2 wherein the plant sterol is α-sitosterol, β-sitosterol, stigmasterol, ergosterol, campesterol, or a mixture of any thereof.

4. The cooking and salad oil composition of claim 3 wherein the edible oil is triolein, soyabean oil, cottonseed oil or a mixture of any thereof.

5. The food composition of claim 1 which is any of those hereinbefore specifically described.

6. A method of making the food composition of any of claims 1—5 in which the plant sterol is dissolved in an intermediate solvent in which it has a greater solubility than in the edible oil, the resulting solution is mixed with the edible oil to which the solubilizing agent has been added, and the intermediate solvent is removed by evaporation.

7. The food composition made by the method of claim 6.

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